

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: WAVE 1 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OR
TO LIMIT THE OPINIONS AND TESTIMONY OF TERI A. LONGACRE, M.D.**

Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon"), submit this Response in Opposition to Plaintiffs' Motion to Exclude or to Limit the Opinions and Testimony of Teri A. Longacre, M.D. ("Motion"). The cases to which this Response applies are identified in Ex. A.

I. Dr. Longacre Is Well-Qualified To Offer Her Opinions.

A. Dr. Longacre is qualified to testify about the pathology of pelvic mesh.

Plaintiffs do not challenge Dr. Longacre's qualifications as a surgical pathologist or a gynecologic pathologist. *See* Motion at 2–5. Rather, Plaintiffs seek to exclude Dr. Longacre's testimony on the grounds that she is not an expert in pelvic mesh products and design. *See id.* at 3. But the opinions Dr. Longacre will offer at trial fall squarely within her expertise as a gynecologic pathologist.

Dr. Longacre is a board certified diagnostic surgical pathologist with a subspecialty in gynecologic pathology, who is currently a Professor of Pathology at Stanford University Medical Center. Pls.' Motion Ex. B, Longacre Report at 1. She trained in Anatomic and Clinical

Pathology at the University of New Mexico, followed by a surgical pathology fellowship at Stanford. *Id.*

In addition to her duties as a pathology professor, Dr. Longacre's role at Stanford includes functioning as the Director of Gynecologic Pathology; the Director of the Gynecologic Pathology Fellowship program, which she founded in 2007; and the Director of the Stanford Hospital Tissue Committee. *Id.* She is also the President Elect of the Association of Directors of Anatomic and Surgical Pathology, based in part on her prior work as a Director of Surgical Pathology at Stanford. *Id.* Dr. Longacre has lectured and published extensively in the field of gynecologic pathology. *Id.* at 1–2.

In her practice, Dr. Longacre routinely examines surgical gynecological specimens with an annual case volume of 5,000 to 7,500 cases. *Id.* at 2. She provides clinical and pathological consultations to physicians at Stanford, which involves formulating diagnoses based on her gross and microscopic review of specimens, and review of relevant clinical information. *Id.*

Dr. Longacre also has experience examining mesh explants in the normal course of her pathology practice. Pls.' Motion Ex. C, Longacre 12/19/14 Dep. Tr. 45:3–46:15 (testifying that she had examined at least 24 transvaginal mesh explants as of December 19, 2014); Ex. B, Longacre 1/19/2016 Dep. Tr. 53:7–55:3 (testifying that she had examined an additional 12 to 24 transvaginal mesh explants since her December 19, 2014 deposition).

Dr. Longacre is eminently qualified to testify about gynecologic pathology in this litigation, such as the body's response to foreign material, including Ethicon mesh products and their integration in the human body; the interaction between tissues and Ethicon mesh products;

and her findings based on her gross and microscopic review of mesh explants.¹ Thus, despite Plaintiffs' assertion to the contrary, Dr. Longacre will offer opinions regarding mesh design features like pore size only as they relate to the body's reaction and interaction with the mesh. Notably, Plaintiffs fail to explain why a pathologist would need specialized experience in meshes in order to testify about the pathology of mesh explants. *See, e.g., Frankum v. Bos. Sci. Corp.*, No. 2:12-CV-00904, 2015 WL 1976952, at *24 (S.D.W. Va. May 1, 2015) (anatomical and clinical pathologist qualified to testify about pathology of mesh material despite lack of training in polymer science or testing of mesh products).

Dr. Longacre will also testify about the numerous methodological flaws inherent in the opinions offered by Plaintiffs' pathologist, Dr. Vladimir Iakovlev. As discussed in Section II, Dr. Longacre will explain that Dr. Iakovlev's opinions on a variety of issues have no foundation in the field of pathology. *See* Pls.' Motion Ex. B, Longacre Report at 9–13. So, while Dr. Longacre will offer opinions regarding issues including the alleged shrinkage or degradation of Ethicon mesh products, she will do so in the context of explaining why Dr. Iakovlev's theories on these issues are medically inaccurate and methodologically unsound.

Dr. Longacre is well-qualified by her “knowledge, skill, experience, training [and] education” to offer such opinions in this litigation, Fed. R. Evid. 702, and the Court should deny Plaintiffs' motion on this basis.

¹ Note that Dr. Longacre does not seek to offer specific opinions regarding the meshes she has reviewed that are not at issue in this litigation. Rather, she will offer opinions regarding the meshes she reviewed in this litigation based, in part, on her understanding of the typical presentation of mesh explants acquired through her clinical experience. *See* Mem. Op. and Order (*Daubert* Motions) at 40, *Bellew v. Ethicon*, No. 2:13-cv-22473 (S.D. W. Va. Nov. 20, 2014) [Doc. #265] (permitting pathologist to offer opinions regarding mesh at issue in case based on his comparison to what he viewed as typical mesh explants based on his clinical experience).

B. Dr. Longacre will not testify about mesh design features and physical properties, the safety and efficacy of Ethicon mesh products, the standard of care for treating SUI and POP, or the general risks of pelvic floor surgery.

Ethicon will not offer Dr. Longacre to testify about mesh design features or physical properties, except as those issues relate to her pathological findings. Nor will Dr. Longacre testify about the safety or efficacy of Ethicon mesh products, the standard of care for treating stress urinary incontinence or pelvic organ prolapse², or the general risks associated with pelvic floor surgeries. *See* Motion at 2–5. Therefore, the Court should deny Plaintiffs’ Motion on these issues as moot.

II. Dr. Longacre is Qualified to Opine Regarding the Flaws in Dr. Iakovlev’s Methodology.

Curiously, Plaintiffs argue that Dr. Longacre—a pathologist whose pathology qualifications Plaintiffs do not challenge—is unqualified to testify about the opinions offered by Dr. Iakovlev—another pathologist. Specifically, Plaintiffs contend that Dr. Longacre is not qualified to criticize Dr. Iakovlev because “she is not an expert in mesh, mesh design or the physical properties of mesh.” Motion at 6. Plaintiffs appear to misunderstand Dr. Longacre’s opinions as they relate to Dr. Iakovlev.

As discussed above, Dr. Longacre does not seek to opine as to the design or physical properties of pelvic mesh. Rather, Dr. Longacre will explain to the jury that many of the opinions offered by Dr. Iakovlev are inconsistent with fundamental principles of pathology and medical facts. Pls.’ Motion Ex. B, Longacre Report at 9–13.

² Although Ethicon does not intend to elicit testimony from Dr. Longacre regarding the standard of care and position statements regarding surgical procedures, Dr. Longacre’s testimony demonstrates that she is highly experienced such standards because they impact the issues she needs to address in her pathology reports on specimens she examines. *See* Ex. B, Longacre 1/19/2016 Dep. Tr. 153:24–155:7.

Dr. Longacre evaluated the photographs included in Dr. Iakovlev's expert report, and found numerous errors in his methodology and findings. For instance, Dr. Longacre will explain that Dr. Iakovlev repeatedly misidentifies normal tissue as scar tissue. *Id.* at 10, 12. She will also testify that Dr. Iakovlev mischaracterizes images depicting the human body's normal and expected foreign body response as evidence of a complication. *Id.* at 10–11. In addition, Dr. Longacre will opine that Dr. Iakovlev misinterpreted photographs allegedly showing damaged circulatory vessels like obliterated arteries and thrombosed capillaries. *See id.* at 12 (explaining that such determinations should not be made without the use of an EVG stain).

Importantly, Dr. Longacre will also inform the jury that it is not possible for a pathologist to conclude that a particular finding caused clinical complications in a patient based solely on a review of pathologic slides. *See id.* at 11 (“It is not possible to determine on the basis of morphology alone any related clinical symptoms.”). Dr. Iakovlev's assertions that he can make such causal conclusions have no basis in the field of pathology. *See, e.g.,* Ex. C, S. Lester, Manual of Surgical Pathology, at 3 (2010) (“It has been shown that pathologists cannot accurately predict clinical information from the glass slides alone.”). In short, Dr. Longacre's testimony will demonstrate that Dr. Iakovlev's analysis is methodologically flawed and inaccurate. In short, Dr. Longacre's testimony will demonstrate that Dr. Iakovlev's analysis is methodologically flawed and inaccurate.

Dr. Longacre will also testify that Dr. Iakovlev's photographs are of limited value to a pathologist due to his deviations from standard pathology practices. Specifically, Dr. Longacre will explain that Dr. Iakovlev's photographs (i) do not provide information regarding the immunostaining process; (ii) have been altered from the original image; (iii) omit paired slides for comparison of different stains; (iv) contain magnification errors; and (v) use high-power

magnification without providing information as to the site under examination. Pls.’ Motion Ex. B, Longacre Report at 9. Dr. Longacre will testify that these methodological flaws preclude appropriate pathological analysis.

In light of her substantial education, training, and experience, it cannot be said that Dr. Longacre is unqualified to opine on Dr. Iakovlev’s pathology photographs.

In addition, Dr. Longacre will explain that the methodology employed by Dr. Iakovlev to detect the purported degradation of Prolene lacks any foundation in the field of pathology. Specifically, Dr. Longacre will testify that although Dr. Iakovlev asserts that he can identify degraded Prolene using certain histological stains and polarized light, as a matter of fundamental pathology, these tools simply do not work in the manner Dr. Iakovlev claims. *Id.* at 10. Indeed, Dr. Longacre will explain that pathologists routinely use chemical stains that identify acidic nucleic acids or basic proteins by forming chemical bonds with those substances, as well as immunohistochemical stains that distinguish between cells and identify cell components. *Id.* But, as Dr. Longacre explains, there is no basis in science—much less in the field of pathology—for Dr. Iakovlev’s assertion that a pathologist can use these tools to identify degradation in polymers. *Id.*

All of these opinions—from Dr. Longacre’s review of Dr. Iakovlev’s pathology photographs to her testimony regarding the generally accepted methods used by pathologists—are clearly within the scope of Dr. Longacre’s expertise derived from her extensive education, training, and experience. Plaintiffs’ arguments to the contrary are without merit, and should be rejected by this Court. *See Fuji Elec. Corp. of Am. v. Fireman’s Fund Ins.*, No. 9:05CV27, 2005 WL 5960354, at *2 (E.D. Tex. Nov. 21, 2005) (explaining that “examin[ation] and critici[sm] of the work of another expert” “is one of the traditional roles of an expert.”); *see also* Fed. R. Civ.

P. 26(a)(2)(D) (providing for the disclosure of rebuttal expert witness opinions “intended *solely* to contract or rebut evidence on the same subject matter identified by another party.”) (emphasis added).

III. Dr. Longacre’s Opinions Are Reliable.

Plaintiffs make numerous assertions in arguing that Dr. Longacre’s opinions in this litigation are unreliable, but Plaintiffs’ claims are without merit. For instance, Plaintiffs contend that Dr. Longacre should be excluded because “she did not conduct any independent research and, instead relied only on what Ethicon’s lawyers provided to her.” Motion at 6. But Plaintiffs’ arguments mischaracterize Dr. Longacre’s opinions and her methodology.

In forming her opinions, Dr. Longacre relied on her education, training, and experience as a pathologist; her analysis of pathology slides and medical records; and her review of medical literature and internal Ethicon documents received from Ethicon’s counsel. *See, e.g.*, Pls.’ Motion Ex. C, Longacre 12/19/2014 Dep. Tr. 7:7–16 (explaining that she relies on pathology records, pathology slides, relevant medical literature, and treating physician depositions); 66:9–24 (testifying that, in addition to literature that she received from Ethicon’s counsel, her opinions are “also based on . . . my general pathology and GYN pathology background and training as well”); *see also* Ex. B, Longacre 1/19/2016 Dep. Tr. 94:19–95:8 (explaining that her opinions regarding whether or not a patient suffers from pain is based on her review of histological specimens and scientific literature, as well as her knowledge and experience as a pathologist).

Having claimed that Dr. Longacre relies “*only* on what Ethicon’s lawyers provided to her,” Motion at 6 (emphasis added), Plaintiffs oddly assert that Dr. Longacre’s pathology opinions are unreliable because she relied “mostly, if not entirely, on her experience as a pathologist,” *id.* at 6–7. They then argue that Dr. Longacre “indicated that the *only* things

relevant to her opinions as a pathologist are the pathology slides.” *Id.* at 7 (emphasis added). Plaintiffs’ fail to explain or cite any authority for their peculiar assertion that it is inappropriate for a pathologist to base her opinions regarding pathology on her experience as a pathologist or her review of pathology slides. In addition, Plaintiffs’ repeated claim that Dr. Longacre’s has only a single foundation for her opinions is belied by the fact that their own Motion identifies at least three different bases for her opinions. Motion at 6–7 (pointing to medical literature, Dr. Longacre’s experience as a pathologist, and her review of pathology slides).

Furthermore, as discussed above, Dr. Longacre’s deposition testimony shows that she bases her opinions on her education, training, and experience, as well as her review of pathology, medical literature, and medical records. Indeed, the same passage of Dr. Longacre’s deposition that Plaintiffs cite in claiming that Dr. Longacre only relies on pathology slides actually states that she based her opinions on her review of pathology slides, medical records, pathology reports, and deposition testimony. *See* Pls.’ Motion Ex. C, Longacre 12/19/2014 Dep. Tr. 57:7–58:4.

In other words, Plaintiffs claims that Dr. Longacre’s opinions are unreliable and unsupported are simply untrue.

Plaintiffs also assert that “Dr. Longacre fails to use any scientific method here that this Court can assess.” Motion at 6. But Dr. Longacre formulated her pathology opinions using the standard methods employed by pathologists. Specifically, she examined pathological slides and identified the presence or absence of certain features and reached a diagnosis, which is the precise methodology pathologists follow in their practice. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 532 (S.D. W. Va. 2014) (explaining that a pathologist used “reliable pathology

methods” where “he reviewed slides, considered the possible causes[], and came to a diagnostic conclusion”).

Dr. Longacre applied this methodology to explain in detail the flaws in Dr. Iakovlev’s methods and opinions. *See supra* Part II; *see also* Pls.’ Motion Ex. B, Longacre Report at 9–13 (providing detailed analysis of Dr. Iakovlev’s photographs and opinions). Thus, despite Plaintiffs’ claim that she “cannot provide any reasoning or any information contrary to Dr. Iakovlev’s opinions,” Dr. Longacre used the well-established methods of pathology to analyze Dr. Iakovlev’s photographs and opinions, and found that his opinions do not withstand scrutiny. Again, this is “one of the traditional roles of an expert” in litigation. *Fuji*, 2005 WL 5960354, at *2.

CONCLUSION

For the foregoing reasons, Ethicon requests that the Court deny Plaintiffs’ Motion to Exclude or to Limit the Opinions and Testimony of Teri A. Longacre, M.D., and that the Court grant any such other and further relief as the Court deems proper under the circumstances.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016 I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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